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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P033577WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/01512	International filing date *(day/month/year)* 04.04.2003	Priority date *(day/month/year)* 05.04.2002
International Patent Classification (IPC) or both national classification and IPC A61K33/14		
Applicant BTG INTERNATIONAL LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.11.2003	13.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Economou, D Telephone No. +49 89 2399-8599

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/01512

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-44 received on 01.04.2004 with letter of 29.03.2004

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-15,30-31

   because:

   ☒ the said international application, or the said claims Nos. 1-15 and 30-31 with regard to IA (see separate sheet, item 1) relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8,11,14-23,26-30,33-36,38-44 (see separate sheet, item 3)
	No:	Claims	1-7,9-10,12-13,24-25,31-32,37 (see separate sheet, item 3)
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-44 (see separate sheet, item 3)
Industrial applicability (IA)	Yes:	Claims	16-29, 32-44 (see separate sheet, item 1c); 1-15,30-31 (see separate sheet, items 1a and 1b)

No: Claims

2. Citations and explanations

see separate sheet

1). a). Claims 1-15 and 30-31 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

b). For the assessment of the present claims 1-15 and 30-31 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

c). The subject-matter of claims 16-29 and 32-44 fulfils the requirements of industrial applicability.

2). The citation appearing in the International Search Report as WATANABE Y ET AL: "POTASSIUM AND HYPERTENSION" NUTRITION REVIEWS, ALLEN PRESS, LAWRENCE, KS, US, vol. 5, PART 1, no. 56, May 1998 (1998-05), pages 151-153, XP001084410 ISSN: 0029-6643, is incorrect.
The correct citation should read SUTER P.M. "POTASSIUM AND HYPERTENSION" NUTRITION REVIEWS, USA, vol. 56, 5 pt. 1, pages 151-153.

3). SUTER P.M. "POTASSIUM AND HYPERTENSION" NUTRITION REVIEWS, USA, vol. 56, 5 pt. 1, pages 151-153 (=**D1**) discloses that the average potassium intake in the USA varies widely between 30 and 100 mol/day (see page 152, right-hand column, forth paragraph. Thus, already normal food intake would decrease blood pressure in a mammal. Hence, the subject-matter of claims 1-3,12,13,24,25,31,32,37 is not novel. Applicant's attention is drawn to the fact that instructions of use are not considered as technical features and therefore the subject-matter of claims 32 and 37 discloses nothing more than the food per se. The subject-matter of claims 6-8,11,28,29 and 33-35 and 38-44 does not involve an inventive step.
ALFONSO SIANI ET AL.: "Controlled trial of long term oral potassium supplements in patients with mild hypertension" BRITISH MEDICAL JOURNAL, vol. 294, 6 June 1987 (1987-06-06), pages 1453-1456, XP001088513 (=**D2**) discloses treatment of patients with 24 mmol/day (Lento-Kalium capsules (KCL);

see page 1453, right-hand column, last four lines from the bottom) which led to a significant blood pressure reduction and concluded that moderate oral potassium supplements are associated with a long term reduction in blood pressure in patients who have mild hypertension (see abstract; last two paragraphs and page 1455, figure 3 and page 1455, right-hand column, first paragraph). Hence, in the light of **D2** the subject-matter of claims 1-7,9-10 and 12-13 is not novel.

The subject-matter of all remaining claims, although novel, does not involve an inventive step since substitution of KCl with another K-salt is known for the skilled person (see **D3**=WO 90 04403), foods as supplements for K^+substitution are known from **D4**(=WO 95 35038; see from p. 4, line 20 to page 5, line 2 and from page 8, line 4 to page 9, line 5 and claims), foods or drinks comprising K^+- ions are known from DATABASE WPI Section Ch, Week 199510 Derwent Publications Ltd., London, GB; Class B04, AN 1995-070227 XP002209847 & JP 06 345660 A (EARTH SEIYAKU KK), 20 December 1994 (=**D5**) and DATABASE WPI Section Ch, Week 199510 Derwent Publications Ltd., London, GB; Class B04, AN 1995-070230 XP002209848 & JP 06 345664 A (TOMITA T), 20 December 1994 (=**D6**) and combination of K^+-supplementation with a further anti-hypertension compound is known from US 4 855 289 (=**D7**). Hence, the skilled person by combining the teachings of **D2** with the contents of any of **D3-D7** would easily arrive to the subject-matter of the application.